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No. 06-372

IN THE

Supreme Court of the United States

FERRING B.V. and
AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MOTION OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

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MOTION FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF SUPPORTING THE PETITION FOR CERTIORARI

Motion for Leave to File Amicus Curiae Brief of the Biotechnology Industry Organization

The Biotechnology Industry Organization ("BIO") respectfully moves this Court, pursuant to Rule 37.2(b), for leave to file a brief as *Amicus Curiae* in support of the Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit. Petitioners have consented to the filing of this brief, but Respondent has declined to consent, thereby necessitating this motion. A copy of the proposed amicus curiae brief is attached.

As more fully explained at page 1 of the attached brief, under "Interest of Amicus Curiae," BIO is a voluntary association of biotechnology industry companies with a strong interest in the strength and predictability of the United States patent system. BIO seeks leave to file this brief on the status of the standards applied for the defense of inequitable conduct, the disproportionate effect the current state of the law has on the biotechnology industry in particular, and the need, from this industry's perspective, for clarification and certainty on this subject.

For these reasons and those set out in the accompanying brief, BIO hereby moves the Court to allow it to appear as Amicus Curiae, and to submit its brief urging the Court to grant the Petition.

Respectfully submitted,

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BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Biotechnology Industry Organization ("BIO") is a trade association consisting of more than eleven hundred member companies, academic institutions, and biotechnology centers. BIO represents and understands the needs, as well as the demanding nature, of the biotechnology industry. This industry provides biotechnology-based products that constitute an important and growing value to the public, from life-saving therapeutics for once untreatable diseases, to cleaner fuels and other environmental-friendly technologies, to heartier and more robust crops to feed a growing world. To create this value, the biotechnology industry invests heavily in research and development.

Patents are vital to the members of BIO. Clear evidence of patent protection attracts the capital necessary for the costly and lengthy development, approval and marketing processes for biotechnology inventions. Therefore, BIO members have an interest in maintaining a strong, stable and viable patent system. BIO is deeply concerned that the Federal Circuit's decision below adversely affects the enforceability of patents.

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1. No counsel for a party authored, in whole or part, this brief. No person or entity other than the *amicus curiae* and its counsel has authored, made any editorial choices regarding or exercised any control over the substance of this brief. Petitioner Aventis Pharmaceuticals, Inc.'s parent corporation Sanofi-Aventis S.A. is a member of BIO. Petitioners Aventis Pharmaceuticals, Inc. itself and Ferring B.V., as well as Respondent Barr Laboratories Inc., are not members of BIO.

BIO has no interest in any of the parties or the outcome of this case.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENTS

The decision in *Ferring* highlights, in dramatic fashion, the unjustifiably low standards for materiality and intent that some panels of the Federal Circuit now apply in an inequitable conduct determination. The court below ruled that an important biotech patent was unenforceable based on omissions in declarations about prior relationships that had no bearing on the validity of the patent or the scientific accuracy of the declarants' testimony. The decision provides no limits on the standard for the materiality of information that should be supplied to avoid a finding of inequitable conduct and it infers intent to deceive based on omission alone. The panel decision goes too far and, if permitted to stand, makes the patent application process unpredictable and more costly, and will make the unenforceability of otherwise valid patents uniformly suspect. This is particularly true for the biotechnology industry which suffers from disproportionate levels of patent attacks claiming inequitable conduct.

Further, BIO submits that the *Ferring* decision needs review because it demonstrates the havoc created by the Federal Circuit's differing standards for materiality and intent in determining inequitable conduct. In the last ten years at least five different materiality standards have been applied in an inequitable conduct analysis, drifting towards more liberal standards of materiality and lower thresholds of intent. Applicants and patent holders need to know what standards

apply to their interactions with the United States Patent and Trademark Office ("PTO") and how to obtain enforceable patents. The Federal Circuit's rulings, culminating in *Ferring*, provide no such guidance. Rather, they encourage litigation based on hindsight conclusions about omissions and thereby discourage investment in an invention because there is no assurance protectable patent rights can be obtained for high-cost and risky developments like biotechnology products and pharmaceuticals.

The issue is exacerbated by the *Ferring* panel's failure to recognize the collaborative and interactive nature of biotechnology scientists' relationships. In this field, in particular, relationships like those found "material" in *Ferring* are commonplace, necessary and nearly always innocent. The panel decision, by inference, and based on omission alone, ascribes sinister motives to accepted conduct and relationships and then leaps to a legal conclusion of patent unenforceability. The impact of the Federal Circuit's inconsistent application of this area of the law on industry in general, and the biotechnology industry in particular, is profound: more allegations of inequitable conduct by aggressive advocates intent on attacking perfectly valid patents protecting valuable research and development investments; increased litigation expenses, resulting in higher priced products, and increased unpredictability that valid patents will be enforceable, resulting in less investment and less innovation. Ultimately, society is the loser. The Court should grant review.

I. THE FEDERAL CIRCUIT'S MULTIPLE MATERIALITY STANDARDS ARE UNWORKABLE AND FURTHER CONFUSION AND UNCERTAINTY.

A. Patent unenforceability for inequitable conduct was created as the ultimate punishment for truly egregious behavior.

The Court in the 1945 case of *Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co.*, 324 U.S. 806 (1945) first recognized the concept of inequitable conduct as a basis for finding a patent unenforceable. There an inventor of one competing application in an interference proceeding filed a fraudulent affidavit. The opposing party learned of the fraud, but did not inform the PTO. Instead, the parties settled the interference and the submitter of the fraudulent affidavit assigned his rights in his application to the other party. The fraud was uncovered in later patent enforcement proceedings. In this extreme situation, the Court recognized that "inequitable conduct" could so "impregnate the application" to render the patent unenforceable as a matter of law. *See Precision Instrument*, 324 U.S. at 818-19. Hence, as created, this was a narrow doctrine to address egregious behavior. That is not how it is now being applied and, as a result, the inequitable conduct defense has become a favorite defense in patent litigation to attack valid and infringed patents. The Court should grant review to clarify the limits of the doctrine's application.

B. The standards for inequitable conduct have eroded based on inconsistent standards for materiality.

In response to *Precision Instrument*, in 1949 the PTO promulgated its first "duty of candor" rule under 35 U.S.C. § 1.56, which prohibited fraud on the Office. Courts implementing *Precision Instrument* generally found that, as with common law fraud, the representation had to be "material" and "intent to deceive" the PTO had to be proven. However, the courts differed on what standards should be applied to the "materiality" and "intent" elements in determining the existence of "inequitable conduct." As to materiality, there were at least three standards used: an objective "but for" standard as in common law fraud, that is, a requirement that the misrepresentation would have affected the issuance of a patent in any circumstance; a subjective "but for" test, requiring proof that the particular misrepresentation caused the specific examiner to approve the patent application; or a "but it may have" standard, requiring only proof that the misrepresentation "might have" influenced the outcome of the prosecution. *See, e.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (collecting and comparing cases).

In addition to these different standards, in 1977 the PTO sought to clarify its own standard for materiality. The PTO's test for materiality, which was arguably broader than any test adopted by any court to that date, required disclosure of any "material information," defined as information "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (1977). In the face of divergent precedent and the PTO's rule, the Federal Circuit could have adopted any number of prevailing

materiality standards in *Am. Hoist & Derrick.* Ultimately, the court adopted the PTO's standard, and for nearly a decade this was viewed as the prevailing standard for "materiality." Inequitable conduct was based on a breach of the applicant's duty of candor to the PTO, rather than any potential misstep that might be viewed as a "misrepresentation" by outsiders to the prosecution process. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

To clarify the "reasonable examiner" standard of materiality and provide more meaningful guidelines for practitioners, in 1992 the PTO adopted a definition of the phrase "material to patentability" in Section 1.56, delineating a series of guidelines, including whether information is cumulative, establishes unpatentability, or refutes an applicant's position. *See* 35 C.F.R. § 1.56 (2005). The Federal Circuit understood that the PTO intended that the materiality of omissions or disclosures by attorneys to it would be judged in accordance with this new standard. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358), 1364 (Fed. Cir. 2003) (quoting Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992) to the effect that rule "has been amended to present a clearer and more objective definition of what information the Office considers material to patentability."); *see also Digital Control, Inc. v. The Charles Machine Works,* 437 F.3d 1309, 1316 (Fed. Cir. 2006) (quoting *Dayco*).

Yet, despite the fact that patent applications have been prosecuted for the last fourteen years under that PTO standard, the Federal Circuit has refused to adopt any single consistent approach to materiality.[2] More recently, a Federal

2. While the patent in suit in *Ferring* was not subject to the PTO's 1992 revisions to Section 1.56, this history is relevant to demonstrate the lack of uniformity in standards before the Federal Circuit.

Circuit panel has held that complying with the requirements set out in Section 1.56 provides no assurance that an entire patent will not be rendered unenforceable based on any of the Court's different "materiality" tests. *See Digital Control, Inc.* at 1315-16. Thus, rather than bringing uniformity to this area of patent law, the Federal Circuit's different rulings have perpetuated a maze of complexity and confusion.

The current unpredictability in application of the inequitable conduct doctrine leaves patent applicants in a quandary and represents a dramatic departure from the intent of *Precision Instruments.* Inequitable conduct is no longer reserved for fraudulent or other egregious conduct, as compliance with the stated rules of the PTO may be inadequate to demonstrate the "clean hands" necessary to defeat a charge of inequitable conduct. As *Ferring* itself shows, mere inferences can be used to satisfy both the "materiality" and "intent to deceive the PTO" requirements, thereby rendering an entire patent unenforceable. *Ferring B.V. v. Barr Labs,* 437 F.3d 1181, 1184, 1191-92 (Fed. Cir. 2006). By the same token, if patent applicants or their counsel provide the PTO with information that is not material to patentability under Section 1.56 but may be deemed material under any one of the five Federal Circuit "materiality" standards, they may still be accused of inequitable conduct because they attempted to conceal the material information from effective review, again rendering the resulting patent unenforceable. In short, applicants are "damned if they do and damned if they don't." This lack of clarity, Federal Circuit inconsistency and dramatic departure from the Court's narrow ruling in *Precision Instruments* are untenable and justify review under Supreme Court Rules 10(a) and (c) to bring certainty to the field.

C. The evaluation of materiality in this case demonstrates the unworkability of the multiple Federal Circuit standards.

The negative impact of the multiple materiality standards being applied by the Federal Circuit is demonstrated in *Ferring*. The examiners suggested the applicant provide declarations of "non-inventors" regarding the meaning of the term "peroral". *Ferring*, 437 F.3d at 1184. They did not request that the applicant supply individuals with no connection at all to the assignee of the applicant's rights. They did not request curriculum vitaes for the affiants. The request was for someone who did not have a direct interest in the outcome of the patent decision.

Even by Respondent Barr's accounts, the applicant met this request. Affiants with impeccable scientific credentials were found and their statements presented in 1986. *Id.*, 437 at 1184 (maj. opinion), 1197-98 (Newman, J., diss.). Four years later, when another rejection was presented, further affiants with similar credentials were asked to address the question. *Id.* 437 F.3d at 1185 (maj. opinion), 1197-98 (Newman, J., diss.). Barr never challenged the veracity of the statements provided and never showed any of the affiants benefited in any way from the patent issuing – rather, the attack on the enforceability of the patent is based on *Ferring's* failure to provide information about prior relationships with the declarants, and the mere possibility that such information could have influenced the examiner's decision to allow the patent to issue.

The panel determined that the applicant "should have" seen beyond the examiners' request that affidavits come from "non-inventors" and construed it as requiring "disinterested"

affiants without "intimate ties to the inventors or Ferring itself." *Ferring*, 437 F.3d at 1190.[3] Apparently that understanding "should have" also extended to voluntary submissions by the applicant four years later in response to a different rejection. That is not what the examiner requested, and goes far beyond the examiners' request for declarations from "non-inventors." Taken literally, the panel's standard would have required declarations from outside experts with no connection to Ferring, the applicants or prosecuting counsel, as anyone with an ongoing relationship to anyone involved with the prosecution would not have been "disinterested." As discussed in further detail in Section II below, this is impractical and contrary to experience in the scientific field.

Even the panel opinion recognizes that it would strain credulity for members of the scientific community to avoid interaction and not call on colleagues to assist with patent prosecutions in appropriate circumstances. *Id.*, 437 F.3d at 1194-95. Nonetheless, this decision states that "at least where the objectivity of the declarant is an issue in the prosecution [which is apparently any time an affidavit is submitted, based on the remainder of the case], the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations." *Id.*, 437 at 1195. Based on *Ferring's* outcome, moreover, the failure in any prosecution at any time not to declare any such relationship is a material omission as a matter of law.

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3. The panel supported this view of what an applicant should have understood in 1986 based on a case announced in 1996. *See Ferring*, 437 F.3d at 1189-90 (discussing *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1581-82 (Fed. Cir. 1996)).

This new "standard" leaves only more questions in its wake. What has to be disclosed? Purely personal relationships? A historic relationship unrelated to the subject of the patent? One time service on an advisory panel with the applicant or another person affiliated with the assignee of the patent? Joint collaboration on an otherwise confidential, ongoing project unrelated to the application? A chance meeting or casual conversation at a scientific conference? *Ferring* thus simply adds another layer of investigation and disclosure for applicants and patent prosecutors, rather than providing any meaningful guidance and rule of law

In sum, practitioners were already walking a fine line between too much disclosure by overwhelming examiners with immaterial information and too little disclosure, thereby opening themselves up to repeated accusations of inequitable conduct. *Ferring* made this balance more precarious, if not impossible, to maintain. Supreme Court review is warranted to clarify this issue.

D. The Federal Circuit's intent standard is also inconsistent and confusing.

Materiality is not the only finding necessary to support a conclusion of inequitable conduct. There must also be evidence of intent to deceive. *See, e.g., GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). *Ferring* also perpetuates the confusion in Federal Circuit precedent with respect to the evidence required to establish intent to deceive the PTO. Despite an *en banc* ruling that "gross negligence" in the form of an unexplained omission will not suffice to find intent, cases such as *Ferring* continue to rule that a mere omission alone can support an inference of intent to deceive.

This, in turn, makes any alleged error or omission the target of post-hoc attack for "inequitable conduct," a situation that should not be permitted to continue.

In *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir 1988) (*en banc* in relevant part), the Federal Circuit overruled prior cases holding that an intent to deceive could be inferred from the nature of the omission itself and that "gross negligence" of the applicant rendered any other explanation than an intent to deceive illogical. *Kingsdown* rejected this approach in large part to minimize the assertions of inequitable conduct being leveled at practitioners and applicants for simple omissions. *See, e.g., Ferring*, 437 F.3d at 1196 (Newman, J., diss.). In *Ferring*, the district court based its finding of intent entirely on the omissions of the relationships between Ferring and certain declarants. In affirming, the majority found that so long as the applicant "should have" appreciated the materiality of the omission and did not provide a sufficiently "credible explanation," that was enough to support a finding of intent to deceive as a matter of law. *Id.*, 437 F.3d at 1191. The panel applied, in effect, a presumption of malfeasance from the supposed magnitude of the omission. *Ferring* demonstrates precisely why *Kingsdown* rejected the "gross negligence" approach – it is inherently subjective and ignores the realities of patent prosecution.[4]

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4. This is not an isolated aberration. *See, Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997), relying on the pre-Kingsdown "should have known" standard of *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984), overruled by *Kingsdown*.*See Kingsdown*, 863 F.2d at 876; *Ferring*, 437 F.3d at 1202. *See also* Lynn C. Tyler, "Kingsdown Fifteen Years Later:What Does It Take to Prove Inequitable Conduct?", 13 Fed. Cir. B.J. 267 (2004) (collecting cases).

This case does not resurrect a stale pre-Federal Circuit split in authority. It highlights the ongoing debate in the Federal Circuit that leaves patent applicants to the chance of what Federal Circuit panel they draw to determine the standards of materiality and intent that will apply to their patents. Supreme Court review is needed to bring clarity and consistency to this important area of the law.

Amicus Curiae respectfully submit that a single, objective standard should apply to finding materiality and intent, and that the presumption of a patent's validity and enforceability should be respected in the inequitable conduct analysis. The Court should grant review.

II. THE HOLDING OF FERRING IMPOSES UNIQUE, COSTLY BURDENS ON THE LIFE SCIENCES COMMUNITY

A. The types of relationships at issue are common in the life sciences community.

The panel decision invalidated a patent based on inferences drawn about relationships that are commonplace, accepted, and even encouraged in the scientific community. Life science research thrives on professional relationships. Scientists in any given specialization tend to have common educational backgrounds, many interpersonal connections, frequently engage in collaborations, and communicate regularly. Such relationships are ubiquitous and multifaceted. They reach across national boundaries, political systems, and cultural barriers just like they transcend the borders of private, public, and academic research. Congress has acknowledged the need to promote cooperative research involving universities, the public sector, and private enterprises by

amending the Patent Act (The Cooperative Research and Technology Enhancement (CREATE) Act of 2004; 108 P.L. 453), and by passing legislation to facilitate public-private research collaborations and technology transfer. The Bayh-Dole Act (96 P.L. 517) and the Stevenson-Wydler Technology Innovation Act (P.L. 96-480), for example, enable Federal agencies to execute license agreements with commercial entities that promote the development of technologies discovered by government scientists, and to enter into cooperative research and development agreements with nonfederal partners to conduct joint research.

In a professional and legal environment that encourages interrelatedness, it is only natural and scientifically reasonable for a life science company to seek to establish relationships with many research groups in its field of interest. Such professional relationships take many common forms, such as basic research collaborations, clinical or field trial participation, speaking engagements, consulting arrangements, grants, postdoctoral support funding, scientific advisory board participation, mentormentee relationships, preceptorships, publication support, transfer of samples, cross-training, industry-sponsored symposia, donations, collegial relationships, and the like.

In the clinical trials area, for example, companies engaged in drug development must often reach out to and establish relationships with large numbers of clinical investigators. For the study of novel breast cancer treatments alone, the National Cancer Institute's website, (http://www.cancer.gov/clinical trial, last visited Oct. 3, 2006) lists 464 open clinical trials as of the writing of this brief, of which 135 are sponsored by industry. Of these, 40 are advanced-stage clinical trials (phase III and IV) that recruit patients at

over 780 clinical centers, hospitals, and clinics in the United States, and at over 770 sites internationally. The magnitude of such research efforts illustrates that relationships between academic and company scientists are a normal and widespread aspect of scientific practice.

Most such relationships involve no exchange of personal remuneration, but focus instead on exchanging information and expertise to advance research projects. In this interactive and fluid professional framework, the question of whether a scientist is "disinterested" or not has little meaning, as the professional relationships at issue in this case illustrate. One declarant, Dr. Czernichow, Professor at the Hopital des Enfants-Malades in Paris, had conducted a clinical study under funding provided by Ferring. *Ferring*, 437 F.3d at 1184; *id.*, at 1198 (Newman, J., dissenting). Another declarant, Dr. Barth, Professor at the Czech Academy of Sciences, had an ongoing joint research relationship with the inventor Dr. Vilhardt. *Id.*, at 1185. Barth and Vilhardt published articles together, spent time in each others' laboratories, and considered each other friends. Some years prior to his declaration, Dr. Barth had apparently conducted studies under a research grant Ferring had provided to his institution, and therefore received occasional financial support to defray the costs of experimental studies in which Ferring was interested. *Id.*, at 1185. A third declarant, Dr. Robinson, division head at the National Institute of Medical Research in London, had briefly been a Ferring employee four years prior to his declaration, and had subsequently had consulting assignments which had ended prior to his declaration. *Id.*

All declarants had respectable scientific credentials, held leading positions at highly-regarded institutions, and received no payment for their statements. It simply strains credulity

to suggest that such scientists would compromise themselves to facilitate the issuance of a United States patent. Nothing in the record so indicates. More distressing to the applicant community, however, is *Ferring's* lack of guidance as to when the cultivation of such unexceptional "ongoing and mutually beneficial relationships," widely occurring in science and falling well within the continuum of common professional interactions, rises to the level of potential bias. The economic and legal uncertainties that now attach to declarations of record in the prosecution histories of thousands of United States patents and pending applications merit review by this Court.

B. The panel decision creates patent uncertainty and increased prosecution costs that will discourage biotechnology investment.

Allegations of inequitable conduct arise with unusual frequency in life sciences cases: approximately 42% of all appeals to the Federal Circuit on the issue of inequitable conduct since the 1988 *en banc* decision in *Kingsdown* involved patents from the biotechnology or therapeutic products sectors[5]. This high frequency of inequitable conduct challenges likely reflects both the high economic value of

5. In preparing this brief, BIO conducted a qualitative survey of published and unpublished opinions in the Federal Circuit, beginning with *Kingsdown* in 1988, that identified 212 opinions in which the issue of inequitable conduct in the PTO was appealed from the lower courts. Of these, 89 involve patents claiming products or methods from the biosciences and biomedical sectors, including agricultural biotechnology, drugs, biologics, medical devices, and diagnostics. These numbers necessarily represent an approximation and do not include appeals that were disposed of by brief orders that do not on their face indicate the nature of the invention at issue, or the legal issues appealed.

life sciences patents, as well as the attractive prospect of being able to capitalize on the patent owner's or licensee's vast investments in bringing the claimed product to market without having to obtain license rights under issued patents.

Few sectors of the United States economy are as dependent upon patents as is the biotechnology industry. It is not uncommon for a biotechnology company to expend hundreds of millions of dollars over more than a decade before collecting its first dollar of product revenue. But investors will not invest where patent rights are increasing by vulnerable to economically inspired accusations of inequitable conduct. Patents are crucial for attracting funding for the development of innovation germinating from university labs and small biotechnology businesses. Without funding, without patents, innovation cannot move from the bench to beneficial applications.

At the patent prosecution level, unfortunately, obtaining patents in biotechnology is costly and increasingly difficult. Not infrequently, applicants need to submit explanatory material and expert declarations to advance their applications. Further costs and uncertainty will now arise from the need to investigate the past, present, or prospective relationships of the declarants to the invention, to the inventor, or to the company or institution to which the invention is assigned or licensed. The applicants' dilemma is worsened by the Federal Circuit's lack of guidance on when a professional relationship purportedly rises to the level of bias such that, absent disclosure, a perfectly valid and infringed patent will be rendered unenforceable.

There are huge consequences to an inference of inequitable conduct, as the life sciences industry is acutely

aware. After decades of research leading to patented products, all could be lost. In *Purdue Pharma L.P. v. Endo Pharms., Inc.* 410 F.3d 690 (Fed. Cir. 2005), *vacated*, 438 F.3d 1123 (Fed. Cir. 2006) for example, the Federal Circuit's eventual reversal of a finding of inequitable conduct was too late to prevent the layoff of approximately half of the patentee's workforce, with serious impact on ongoing drug research programs. Had clear, objective standards of materiality and intent been applied in the first instance, that result could have been avoided.

Almost assuredly the effort and the logistics required in trying to comply with the *Ferring* standards during patent prosecution will tax already limited patent budgets. In effect, decades of issued patents, allowed by habitually reluctant examiners after consideration of expert declarations, are now legally suspect on the basis of professional relationships that are so common in normal scientific practice that researchers would not deem them worthy of special mention. Going forward, even well-meaning and thorough applicants can never be assured that their efforts would satisfy the *Ferring* standards, or any of the five Federal Circuit inequitable conduct "standards."

Yet to justify the vast investment of time and money in experimental products whose likelihood of ever reaching the marketplace is low, companies depend on the strength and enforceability of their patents. It is the certainty that comes from knowing that an invention discovered ten or more years prior to coming to market can be protected that provides the incentive for investors to fund such high-risk, long-term biotechnology products. But investors will not invest where patent rights can be easily subjected to unforeseeable

accusations of inequitable conduct. This profound legal uncertainty, and its chilling effect on life science innovation, deserve the attention of the Court.

CONCLUSION

For the reasons set forth above, this Honorable Court should grant the Petition for Certiorari.

Respectfully submitted,

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